



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,110	07/28/2003	Sergey Gazenko		3544

7590
Sergey Gazenko
1106 Park Side Ln.
Mason, OH 45040

10/27/2005

EXAMINER

HARLE, JENNIFER I

ART UNIT	PAPER NUMBER
----------	--------------

1654

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,110

Applicant(s)

GAZENKO, SERGEY

Examiner

Jennifer I. Harle

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,8 and 9 is/are rejected.
- 7) ☐ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 6-9 are pending. Claims 1-5 were canceled by Amendment dated August 18, 2005.

Priority

2. As no arguments or response to the examiner's statement regarding granting of priority has been received. The examiner's arguments are incorporated by reference, the request for priority is denied and made final.

Drawings

3. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

Specification

4. The amendment filed August 18, 2005 is objected to under 35 U.S.C. 132(a) because it introduces a plethora of new matter into the disclosure, including the specification, drawings and claims. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is, for example as follows: the underlined portions of [001], [002][003], [004], [005], [006], [007], deletion of for cells in [008] because toxicity could be for organisms that are not cellularly based, deletion of could in [0008] making it a positive recitation rather than a probable recitation,

Art Unit: 1654

[009], [011], [0012], [013], [014], [015], [016], [017] (also note that there is a change to microscopy from microscope, which can have different meanings as microscopy is different than how microscope was used originally), [018], [019], [028], [029], [030], [031], [032] [033], [0334], [035], Description of the Drawings is replete with new matter, for examples, as it adds new items to the figures and descriptive elements, as well as new drawings, [036]-[040], [041], [042, [043], [044]-[070]; Drawings – new drawings are added adding new matter, writing is added to the drawings along with new components, i.e. Fig. 5 - manifold, air pump, syringe, anti-body-enzyme conjugates, see also Fig. 6 and 4 (with additional component) Fig. 2, Fig. 3; Claims see, e.g. (picoliter format: 1-500 picoliters, microchannels that are open from both sides and attached to a filtration material, with a filter attached to one side of the micro-channel plate for trapping cells, attaching solid or liquid nutrient media to the side of the filter, replacing the micro-plate with a filter ..., replace the micro-plate with a filter..., light scattering (turbidity), or natural fluorescence ..., biomolecules, after cleaving by specific indicator enzymes.

Applicant is required to cancel the new matter in the reply to this Office Action. If Applicant considers that the additions to the Specification should not be considered new matter, Applicant should point out specific references in the original specification, which particularly and distinctly support each and every addition to the Specification, Drawings and Claims. In the event that Applicant desires to retain the changes to the Specification but they are still deemed new matter, the Applicant can file a Continuation-in-Part. See MPEP 201.08 and 201.11-201.11(a). If Applicant has any questions regarding continuations-in part and their filing, Applicant is directed to contact the PTO help desk as set forth previously or the official web site. If further assistance is needed, Applicant is encouraged to contact the examiner.

Art Unit: 1654

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 6 – replacing the micro-plate with a filter ... (Could not find any support in the specification – the microchannel plate is never disclosed to be replaced by a filter).

6. Claims 7 and 8 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 recites that the micro-colonies don't need additional coloration, whereas in claim 6, they are already colored by absorbent or fluorescent dyes.

Claim Rejections - 35 USC § 112

7. The 35 US § 112, first paragraph, rejection as failing to comply with the enablement rejection is withdrawn in light of Applicant's amendment to the Specification. However, if the amendments to the Specification were withdrawn, the rejection would be reinstituted.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. How can the micro-plate be replaced by a filter in step 5 when it has already been replaced by a filter in step 4? It is unclear as to how you will correlate the number of live cells in the initial sample with those in the micro-colony. In claim 9, it is unclear what is

Art Unit: 1654

being cleaved by the specific indicator enzymes, is it the cell, is it a receptor, is it portions of the micro-colony from each other?

10. The term "rapid analysis" and "long and thin" in claim 6 are relative terms which renders the claim indefinite. The term "rapid analysis" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, while it does provide example in conjunction with parameters for the long and thin channels, it does not specifically set forth what rapidly means. It is suggested that Applicant utilize a range of times and parameters for long and thin.

11. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what after reaction with cells structures or biomolecules has to do with coloration and detection of microcolonies, and where it occurs in the process of claim 6 and how it is carried out.

Conclusion

12. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

Art Unit: 1654

A listing of registered patent attorneys and agents is available on the USPTO Internet web site <http://www.uspto.gov> in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

13. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below or the filing of a Continuation in Part, as set forth above.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee of \$500.00 if a large entity and \$250.00 if a small entity.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice

Art Unit: 1654

of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer I. Harle
Examiner
Art Unit 1654

October 25, 2005



CHRISTOPHER R. TATE
PRIMARY EXAMINER